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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,610	09/26/2001	Adam S. Cantor	56032US022	8132

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EXAMINER	
JOYNES, ROBERT M	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/965,610	CANTOR ET AL.	
	Examiner	Art Unit	
	Robert M. Joynes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 23-38* is/are pending in the application.

4a) Of the above claim(s) *22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 23-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants' Request for Continued Examination filed on January 9, 2004. Claims 1-21 and 23-38 are pending. Claims 37 and 38 have been amended.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-21 and 23-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garbe et al. (WO 96/08229) in view of Cleary (EP 0483105 A1). Garbe teaches a transdermal drug delivery device comprising a backing and a matrix comprising a copolymer, a softener and a drug (Page 2, lines 5-23). The copolymer comprises one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 10 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 10 carbon atoms in the alkyl group; one or more ethylenically

unsaturated B monomers copolymerizable with the A monomers and a macromonomer copolymerizable with the A and B monomers (Page 2, lines 5-23). The A monomers are taught on Page 4, lines 3-14. The B monomers are taught on Page 4, line 15 through Page 5, line 12. The macromonomers are taught on Page 5, line 13 through Page 8, line 28. Polymethylmethacrylate macromonomers are preferred (Page 6, lines 17-18). The macromonomer is generally present in an amount of not more than 30% by weight based on the total weight of all monomers in the copolymer (Page 5, lines 2-23).

The softeners of the delivery device include fatty acids, fatty alcohols, fatty acid esters as well as drugs that act as softeners (Page 8, line 29 – Page 10, line 15). Softeners can be included in amounts up to 60% by weight of the matrix (Page 10, lines 7-15).

Garbe further contemplates various drugs for delivery by the device including analgesics such as fentanyl (Page 12, line 7 – Page 13, line 20). The drug is present in the transdermal device in an amount of about 0.01 to about 30 percent by weight (Page 13, lines 16-18). Also, the drug is substantially fully dissolved, and the matrix is substantially free of solid undissolved drug (Page 13, line 18-20).

Garbe does not expressly disclose the exact concentration ranges in the instant claims nor does it specifically exemplify that fentanyl in the drug delivered. Fentanyl is listed as a possible acceptable drug for transdermal delivery. The concentration range given for the drugs recited completely encompasses the instant claimed range.

Cleary teaches a transdermal delivery device comprising fentanyl and absorption enhancers in a matrix (Page 10, Claims 1-7). The absorption enhancers are fatty acid

esters or fatty alcohol ethers (Page 10, Claim 1). Clearly teaches that fentanyl is known to be delivered by a transdermal device.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a transdermal delivery device wherein a copolymer matrix containing acrylate and methacrylate monomers and a macromonomer further contains fentanyl and enhancing adjuvants. Garbe teaches the delivery device and lists suitable drugs for delivery by the device. Cleary teaches that fentanyl is delivered transdermally in the presence of absorption enhancing agents. It is obvious to place fentanyl in the delivery device of Garbe.

One of ordinary skill in the art would have been motivated to do this to provide a transdermal drug delivery device that allows dissolution of drug and relatively heavy loading with oily excipients, maintains contact with the skin and can be removed cleanly from the skin.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed January 9, 2004 have been fully considered but they are not persuasive. Applicants argue that the prior art fails to suggest a transdermal delivery system that contains about 8% to about 30% fentanyl wherein the composition is substantially free of undissolved fentanyl.

The Examiner finds these arguments unpersuasive. The prior art (Garbe) teaches a transdermal delivery system wherein the active agent to be delivery is present from about 0.01% to about 30%. This range completely encompasses the range recited in the instant claims. Further, the prior art teaches that fentanyl can be the active agent in the transdermal device. The secondary reference, Cleary, teaches that fentanyl is known to be delivered through transdermal devices. Still further the prior art states that the drug is substantially fully dissolved, and the matrix is substantially free of solid undissolved drug (Page 13, line 18-20). Therefore, the prior art does teach transdermal devices that contain fentanyl in amount of about 0.01% to about 30% wherein the composition is substantially free of solid undissolved drug. Any arguments to the contrary are not persuasive.

To state the argument another way, the prior art teaches a transdermal delivery system that is the same as the system recited in the instant claims. The copolymers used to form the matrix are the same. Applicants admitted in the December 3, 2003 interview that the polymers recited in the instant claims are not novel copolymers but rather copolymers that are know in the art for this exact purpose. Further, the purpose of the device taught by the prior art is to prepare a transdermal device wherein the drug

to be delivery by said device is substantially free of undissolved drug. This purpose is the same as the recited intention of the instant claims. The prior art also lists fentanyl, the recited drug of the instant claims, as a drug that can be delivered by such a transdermal system. Generally, the prior art teaches that the transdermal system can contain 0.1% to 30% of the drug. The secondary reference is used to show that fentanyl is delivered by transdermal devices. Applicants argue that the prior art does not exemplify a device wherein the fentanyl is present from 8-30%. While this is true, the reference itself teaches the drug can be delivered by the device and the drug can be present from 0.1% to 30%. This range, again, completely encompasses the range recited in the instant claims. Those of ordinary skill in the art routinely determine concentration ranges for drug delivery devices. Therefore, the prior art suggests a transdermal delivery device wherein fentanyl is the drug and the drug can be present from 0.1% to 30%.

It is the position of the Examiner that the prior art is suggestive of the device of the instant claims. Further, the Examiner fails to see the criticality in the recited concentration ranges for the fentanyl and the length of time the drug is to be delivered. Absent a clear showing of the criticality, the determination of the particular concentrations or time of delivery is within the skill of the ordinary worker as part of the process of normal optimization.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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